

# REVIVE!

## OPIOID OVERDOSE REVERSAL FOR VIRGINIA

### WHITE PAPER

Office of Substance Abuse Services

Virginia Department of Behavioral Health and Developmental Services

Version 2.2, Revised October 30, 2014

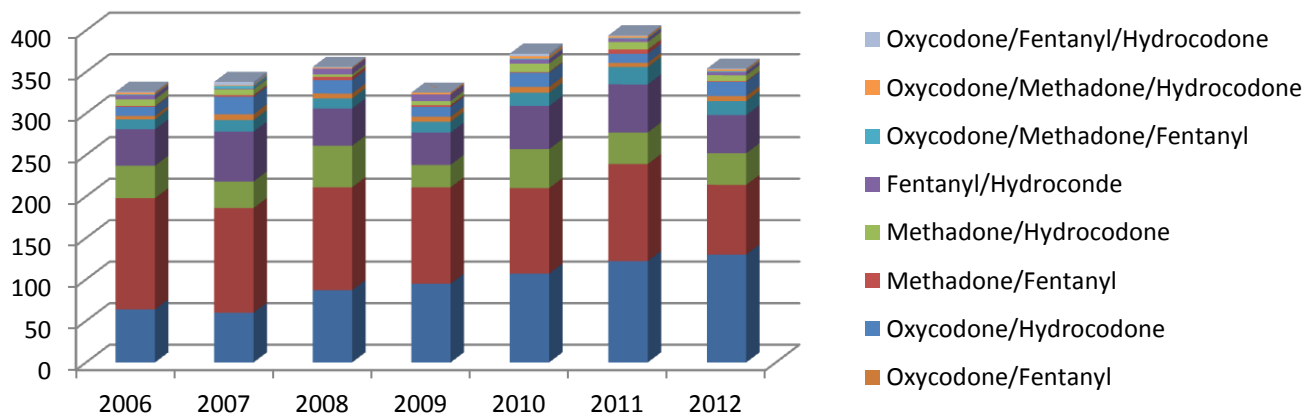
#### I. Purpose

REVIVE! is a pilot program of the Commonwealth of Virginia which makes naloxone (Narcan<sup>®</sup>) available to Lay Rescuers to reverse opioid overdose emergencies. A collaborative effort led by the Virginia Department of Behavioral Health and Developmental Services (DBHDS), the program includes the Virginia Department of Health, the Virginia Department of Health Professions, recovery community organizations such as the McShin Foundation, OneCare of Southwest Virginia, the Substance Abuse and Addiction Recovery Alliance of Virginia (SAARA), and other stakeholders.

#### II. Background

Virginia has been severely impacted by opioid abuse, particularly the abuse of prescription drugs. In 1999, the first year for which such data is available, 23 people died from abuse of fentanyl, hydrocodone, methadone, and oxycodone (the leading prescription opioids abused, commonly referred to as FHMO). By 2003, that figure had increased to 137 (an increase of 595%). In 2012, the most recent year for which complete data is available, 336 individuals died from the abuse of FHMO, an increase of 1,461% since 1999. The deaths related to all opioids, including heroin, are even higher. In 2011, for the first time ever, drug-related deaths happened at a higher per capita level than motor vehicle crashes -- 9.6 deaths per 100,000 for drug-related deaths versus 9.4 deaths per 100,000 for motor vehicle crashes.<sup>1</sup> This upward trend in opioid-related deaths continues, as preliminary data from the OCME indicates that opioids were responsible for 648 deaths in 2013.<sup>2</sup>

### FHMO Combination Deaths, 2006-12



<sup>1</sup> <https://www.vdh.virginia.gov/medExam/documents/2013/pdf/Annual%20Report%202011.pdf>

<sup>2</sup> Virginia Medical Examiner Data System, Office of the Chief Medical Examiner, Virginia Department of Health.  
<http://www.vdh.virginia.gov/medexam/>

Naloxone, a prescription medication, is a specific opioid antagonist drug that reverses the effects that opioids have in the brain. When a person overdoses on opioids, the opioid overwhelms specific receptors in the brain, slowly decreasing respiration before finally stopping it altogether. Naloxone has a very high affinity for these receptors and effectively pushes the opioid off of the brain receptor. This action allows a person to resume respiration. Naloxone has been used for years by emergency medical technicians and emergency room doctors to reverse opioid overdose emergencies. Outside of this singular purpose, naloxone has no effect on the body, and poses no danger to anyone who accidentally administers it to themselves or someone else.

Naloxone is a proven public health response to the epidemic of opioid overdose emergencies. The Centers for Disease Control and Prevention indicate that since 1996, when the first program to distribute naloxone to Lay Rescuers was implemented, 53,032 persons received training on administering naloxone. Those individuals have saved 10,171 lives by administering naloxone to individuals who were experiencing an opioid overdose emergency.<sup>3</sup>

When naloxone is administered by a trained emergency medical professional, it is injected. However, most programs relying on Lay Rescuers use a mucosal atomizer device (MAD) that attaches to the pre-filled syringe containing the medication. This device enables the medication to be administered nasally, which is just as effective. Using the MAD reduces the risk for needle-sticks in the Lay Rescuer that could potentially transmit infectious diseases or infection to the victim, or air bubbles in the medicine, which could prove fatal to the overdose victim. REVIVE! is utilizing the MAD in its pilot programs. Intranasal administration of naloxone has been found to be just as effective as muscular injection in a recent study performed by Lightlake Therapeutics Inc. in conjunction with the National Institute on Drug Abuse.<sup>4</sup>

The Food and Drug Administration recently approved a pre-filled auto-injection device for the administration of naloxone (Evzio<sup>®</sup>). DBHDS is currently evaluating whether this device might play a future role in REVIVE!

### **III. Legislation**

The 2013 Session of the General Assembly, under the sponsorship of Delegate John O'Bannon, enacted House Bill 1672 (<http://1.usa.gov/1mOsgfhf>), which authorizes the use of naloxone by a Lay Rescuer. The legislation permits a prescriber to prescribe naloxone to a person for use on a person who may be unknown to the prescriber ("non-patient specific" prescribing), the only instance in the Commonwealth in which a prescriber is allowed to prescribe for someone with whom he does not have a bona fide patient relationship. It also provided civil immunity (also known as "Good Samaritan" protection) to individuals who participate in the pilot. The legislation directs DBHDS to be the lead agency for conducting pilot programs on the administration of naloxone to counteract the effects of opioid overdose emergencies. To conduct these pilots, DBHDS chose two regions of the Commonwealth, the Richmond metropolitan region (the city of Richmond and counties of Chesterfield, Henrico, and Charles City) and the far southwestern region (cities of Bristol and Norton and counties of Buchanan, Dickenson, Lee, Russell, Scott, Tazewell, Washington and Wise). These are two regions of the Commonwealth that have experienced significant impact from opioid abuse. DBHDS is currently evaluating other areas for inclusion in the pilot once the pilot has been initially implemented. The General Assembly appropriated \$10,000 to execute the pilot.

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<sup>3</sup> <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6106a1.htm>

<sup>4</sup> <http://www.sacbee.com/2013/12/03/5967297/initial-data-from-lightlake-therapeutics.html>

#### **IV. Training**

DBHDS and its partners determined that, even though not mandated by legislation, training is a vital part of the successful implementation of the program. Therefore, everyone seeking to obtain a prescription for naloxone in the pilot must attend a training event and register as a Lay Rescuer. The training covers the following topics:

- Identifying causes and risk factors for opioid overdose emergencies
- Clarifying common myths about responding to an opioid overdose emergency
- Explaining why naloxone is now available
- Providing live, step-by-step training on the administration of naloxone

The initial training of trainers (TOT) was provided by Joanna Eller, Clinic Director at CRC Health Group. Ms. Eller's experience includes working with Project Lazarus, one of the first naloxone distribution programs in the country. The training curriculum has been developed specifically for REVIVE! to address the specifics of Virginia's law. Participants in the initial TOT are providing training in the pilot areas to expand the training effort as much as possible. DBHDS has created a training agreement (see Appendix A) that must be executed by those who seek to be trainers for REVIVE! The training agreement outlines expectations for trainers, including fidelity to the training curriculum and that training events are to be provided at no cost.

As the training agreement indicates, TOT participants will be encouraged to plan and lead training events targeted to individuals in the pilot areas who desire to be Lay Rescuers. Assistance for this planning will be provided by DBHDS as needed, including publicizing events and providing training materials.

Lay Rescuers are those who live in one of the designated pilot areas and have attended one of the trainings described above. When individuals complete the training, they will be registered as a Lay Rescuer for REVIVE! DBHDS will maintain a database of these Lay Rescuers. The trained Lay Rescuers will also receive a kit bag that contains the tools and supplies necessary to respond to an opioid overdose emergency – latex-free gloves, a rescue breathing mask, a mucosal atomization device (MAD), and an instruction card for the administration of naloxone. Once they have this kit, they can then obtain a prescription for naloxone and have the knowledge and materials necessary to save the life of a person experiencing an opioid overdose emergency.

#### **V. Registration**

As part of training events, Lay Rescuers will be required to submit a registration. This registration will include the following information:

- Name and address
- Date of Birth
- Gender
- Race
- City/County of Residence
- Stakeholder group affiliation (if applicable)
- How person heard about training
- Reason for attending training
- Willingness to train others

These registrations will be collected by DBHDS and entered into a database. With this information, DBHDS will be able to track how many Lay Rescuers are available in pilot areas, as well as general demographic information. With their kit, Lay Rescuers will also receive a return card that they can submit once they have administered naloxone to an individual experiencing an opioid overdose emergency. This will help DBHDS track usage as well as monitor the need for more kits and prescription refills. DBHDS will also track the number and location of trainings provided to ensure that the pilot areas have equitable access to training opportunities.

## **VI. Medication Access**

Prescriptions for naloxone must be obtained from a doctor and can be filled at various retail locations. These prescriptions will be for the pre-filled Luer-Jet syringe of naloxone, which is what Lay Rescuers will be trained to use. These syringes are fully compatible with the MAD included in the rescue kit. Once the Lay Rescuer has this medication, their rescue kit is complete and she or he will be able to respond to an opioid overdose emergency. In full pilot implementation, Lay Rescuers will need to obtain a prescription for naloxone and take it to a retail pharmacy to be filled. DBHDS has worked with medical professionals in the far Southwest Virginia pilot area to provide prescriptions for all trainers and Lay Rescuers. DBHDS is working with stakeholders in the Richmond metropolitan area to implement a similar protocol.

## **VII. Associated Costs**

Trainings and rescue kits are provided at no charge to Lay Rescuers. DBHDS will be providing the funding to cover these supplies and events. Individuals will need to pay for associated doctor visits (when necessary) to obtain prescriptions, as well as paying for the medication. DBHDS is exploring options to help defray the cost of medication, and a voucher system to subsidize the cost of naloxone has been implemented in the far Southwest Virginia pilot area thanks to a donation from the Appalachian Substance Abuse Coalition.

## **VIII. Eligibility**

Due to the language of the legislation, current eligibility for REVIVE! is limited to the jurisdictions mentioned above, the Richmond metropolitan region (the city of Richmond and counties of Chesterfield, Henrico, and Charles City) and the far Southwest Virginia region (cities of Bristol and Norton and counties of Buchanan, Dickinson, Lee, Russell, Scott, Tazewell, Washington and Wise). The pilot areas may be expanded once the currently identified pilots have become operational.

## **IX. Evaluation and Outcomes**

Each kit will include postcards for Lay Rescuers to mail back to DBHDS when they have administered naloxone. The card includes the following questions for the Lay Rescuer to answer:

- Date and time of the opioid overdose emergency
- Did you call 911?
- Did the person survive the opioid overdose emergency?
- How many doses of naloxone did you administer?
- Did you have any problems using the kit or administering the naloxone?
- Name and address (if a new rescue kit is needed)

Each card will also have an index number, which will link the rescue kit to the location from which it was initially distributed. This will help DBHDS track usage, community engagement, and plan for future resource needs. The number of return cards received, along with the answers on the cards received and qualitative data from Lay Rescuers and stakeholders, will help DBHDS perform evaluation of REVIVE! This information will be included in a final report for REVIVE! that will be submitted to the General Assembly by DBHDS in December 2014.

## **X. Progress**

To date, REVIVE! has trained 75 trainers, who have trained 285 Lay Rescuers. To date, no successful administrations of naloxone have been reported.

## **XI. Frequently Asked Questions**

Some concerns have been raised about making naloxone available to Lay Rescuers in the community. Here are some frequently asked questions about naloxone, as well as DBHDS responses to those questions.

### **Does the availability of naloxone cause drug users to increase how often they use, or how much they use?**

There are no scientific data to support the assertion that naloxone availability leads to increase or more intense drug use, but there is scientific data that suggests that the availability of naloxone **saves lives**.<sup>5</sup> For more information on this data, please click this link for a number of naloxone program case studies: <http://bit.ly/1jnsphw>.

Individuals overdose because the strength of the opioid they have taken is greater than that for which the individual has developed tolerance. Over time, the brain “gets used to” a certain level of opioid which causes the brain to build up tolerance. This is why prescribers who use opioid pain medication for chronic pain sufferers must increase the dosage of opioid pain medications or change to a medication with a different opioid chemical structure. If the half-life (the length of time the drug stays in the person’s system, even after the analgesic effect has worn off) of the new medication is longer than the medication the patient has been using and the pain returns, the patient may inadvertently overdose, unless he or she has been warned by the prescriber.

Individuals who abuse opioids to achieve the “high” have to increase the amount of the drug they are using to achieve this feeling. When using heroin, the person may not know the strength of the drug. Furthermore, if the person is an inexperienced user or has not used in a long-time, he or she could accidentally overdose because the strength of the heroin was greater than that for which the individual had physiological tolerance. In addition, heroin suppliers may have mixed several opioids together or have mixed opioids with other drugs to amplify the effect of the opioid, which can increase the likelihood of opioid overdose emergency.

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<sup>5</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3008773/>.

**Does the availability of naloxone deter drug users from seeking treatment?**

There is no scientific data that support this opinion, which assumes that people who abuse drugs do so by choice. Addiction is a brain disease that affects an individual's brain chemistry.<sup>6</sup>

**Are Lay Rescuers competent to administer naloxone?**

Naloxone is a drug that has no side effects, and will have no impact if accidentally administered to someone who is not experiencing an opioid overdose emergency or is accidentally self-administered (such as in the case of a child).

Administration of naloxone to someone experiencing an opioid overdose emergency may cause acute withdrawal (which can lead to vomiting and aspiration) or pulmonary edema and cardiac arrhythmias, and the effect of naloxone may wear off prematurely, requiring multiple administrations.<sup>7</sup>

Lay Rescuers who are participating in REVIVE! will receive comprehensive training on recognizing an opioid overdose emergency, administering naloxone, and encouraging the individual to seek treatment for their drug use. Individuals will be prepared for the possibility of withdrawal symptoms, and will understand the need to stay with the victim until First Responders arrive. Most importantly, Lay Rescuers will understand that calling 911 is a vital and necessary part of responding to an individual who is experiencing an opioid overdose emergency.

If your question has not been answered in this document, please contact Jason Lowe at [jason.lowe@dbhds.virginia.gov](mailto:jason.lowe@dbhds.virginia.gov) or (804)786-0464 for more information.

**XII. Acknowledgments**

REVIVE! would not be possible without the assistance of many public and private partners, who DBHDS would like to acknowledge for their invaluable assistance.

Boston Public Health Commission  
Chicago Recovery Alliance  
Delegate John O'Bannon, R-73  
Joanna Eller  
Harm Reduction Coalition  
The McShin Foundation  
Massachusetts Department of Public Health  
Multnomah County (OR) Health Department  
New York City Department of Mental Health and Hygiene  
Ed Ohlinger  
One Care of Southwest Virginia  
Project Lazarus  
SAARA Recovery Center of Virginia  
San Francisco Department of Health/DOPE Project  
University of Washington Alcohol and Drug Abuse Institute  
Virginia Department of Health  
Virginia Department of Health Professions

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<sup>6</sup> <http://www.npr.org/templates/story/story.php?storyId=17578955>

<sup>7</sup> <http://www.ncbi.nlm.nih.gov/pubmed/17367258>

## Appendix A

Version 2.2

Revised October 30, 2014

### AGREEMENT FOR REVIVE! TRAINERS

The Virginia Department of Behavioral Health and Developmental Services (DBHDS) needs to ensure that all participants have a common understanding and investment in the outcome of the pilot, especially those who will be providing trainings for Lay Rescuers. DBHDS recognizes that the success of REVIVE! depends on how well it is implemented in the community and is grateful for the time and expertise of the community stakeholders who are participating in making REVIVE! a success. Consistent, quality training is an essential component of the successful implementation of REVIVE! and DBHDS appreciates the time and investment of individuals who are volunteering to provide training.

Please read the following carefully and sign and date it at the end.

#### Reimbursement for Expenses

##### Mileage

DBHDS will reimburse participants for their mileage incurred in traveling to training events, using the current state rate (based on the U.S. IRS rate). However, due to the relatively short length of the training, reimbursement for overnight stays and/or meals WILL NOT be provided. To be reimbursed, participants will be required to submit a signed state travel voucher that includes the trainer's social security number. This form, along with instructions on how to complete, will be included in the Training Handbook that will be provided at Training of Trainer (TOT) events. Instructions for completing this form will be provided as part of the TOT.

##### Naloxone

Because trainers are providing information about how to use a medicine that must be prescribed by a licensed health practitioner, DBHDS has made arrangements to provide trainers with a prescription that **must be filled prior to providing a training**. This medication is part of the training kit. **Each trainer is responsible for getting the prescription filled and for paying for it**. Once a trainer has provided training to 30 individuals and submitted their names to DBHDS for inclusion in the REVIVE! database, the trainer can submit the receipt from the pharmacy which filled the prescription for reimbursement. The receipt must have the prescription number, the trainers name, the date filled, the name of the drug (naloxone) and the amount paid. This prescription is for the training kit; you should get your own physician to provide you with a prescription for your personal kit.

#### Supplies, Equipment and Curriculum

##### Training Kit

Use **only** the materials provided in the kit provided by DBHDS. In addition to the Luer-Jet syringe with naloxone, each trainer will have access to a kit that includes:

- Latex-free gloves
- Rescue breathing masks
- Mucosal atomizer devices
- Information card, return cards, and "I've Received Naloxone" stickers

Other materials required for leading a REVIVE! training include:

- CPR Mannequin (each pilot area will have access to four mannequins, and others might be available through local law enforcement, fire and rescue, or health departments)
- Extra training kit materials

- Printed copies of REVIVE! Training Guide to distribute
- Hard copies of Registration Form for individuals who don't register
- Sign in Sheet
- Evaluation Forms
- Laptop Computer and Data Projector, and PowerPoint slides (not necessary, but may be useful)

A CD is included with the Training Handbook that has the PowerPoint presentation, instructional videos, and other forms and documents. These can be used at trainings where internet access is not available.

Once you have attended a TOT and are ready to lead a training for Lay Rescuers, please schedule your training and send the following information to Jason Lowe:

- Details of training – Location, date, and time (including physical address)
- Number of trainees (to provide you with kits for each trainee)

Please submit this information via email at least 10 calendar days before the training so that DBHDS has time to send you the kit bags and extra training materials you will need to hold your training, as well as providing additional publicity for the training event on the DBHDS website. After the training, use the provided self-addressed stamped envelope to submit the sign in sheet, registration forms, and evaluation forms so that those Lay Rescuers can be added to DBHDS' database.

## **Logistics**

### Training Locations

Use only locations that are safe, easy to find, and offer safe (and preferably free) parking. Make sure that bathrooms are available. No funds are available to pay for training space, but free space may be available at local health departments, community services boards, churches, schools, community centers, and libraries in the pilot areas. Training locations that provide free internet access are not necessary, but are encouraged.

### Publicity

DBHDS will provide online posters and press releases that can be "filled in" with specifics for use in publicizing training opportunities. Use only DBHDS-approved materials. Take advantage of community newsletters, press releases, media outlet notifications (local television and newspaper, cable access), social media, and other methods available. Ask local health departments, community services boards, and pharmacies if you can put up posters advertising REVIVE! training events.

Please refer any press inquiries to Maria Reppas, DBHDS Communications Director, at [maria.reppas@dbhds.virginia.gov](mailto:maria.reppas@dbhds.virginia.gov) or (804)887-7398. You may also contact Maria for more ideas about publicizing your training event.

## **Managing the Training Event**

REVIVE! trainers cannot charge individuals to participate in training to become a Lay Rescuer.

Arrive early to set up the training venue and be prepared!

Follow the curriculum guide as it is written. If you find resources that you think would be helpful, please send them to Jason Lowe at [jason.lowe@dbhds.virginia.gov](mailto:jason.lowe@dbhds.virginia.gov) or DBHDS, PO Box 1797, Richmond, Virginia 23218 for consideration. You can also contact Jason at (804)786-0464.

Allow about one hour for each REVIVE! training event. Limit group size to no more than 25 per trainer; more than that will make it difficult to provide Lay Rescuers with a chance to practice and ask questions.

Lead the training confidently and sensitively. The issue of opioid overdose emergencies may act as a trigger for some individuals, reminding them of negative memories. Be sensitive to this as you are leading the training, and help those who are triggered to process their feelings and to find additional professional or peer-led help as necessary.

If someone asks you a question during the training and you are not sure how to answer, it's perfectly fine to tell them that you don't know but will get in touch with them later with the answer; then make sure you follow through.

This training event is solely for the purposes of REVIVE! You should not publicize, market, or promote any other product, agency or event (unless preapproved) during this training.

Finally, please recognize that any information shared by trainees during a training event is considered confidential and is not to be shared to anyone except as required by state law.

### **Other Expectations**

Lead as many training events as you have the opportunity for. No specific number of trainings is required, but we strongly encourage you to lead trainings when requested and when time allows. In your capacity as a REVIVE! trainer, you are representing DBHDS in addition to the agency or organization you are employed by or representing. As such, you are being held to a high standard of professionalism.

I signify that I have read, understand and agree to comply with the statements in this document by my signature, below.

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Printed Name of REVIVE! Trainer

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Signature of REVIVE! Trainer

Date

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Jason Lowe, DBHDS

Date